

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. James Voeller on Friday, August 26, 2011. In Applicants' most recent submission, claims 17 and 20 depended from claim 4. However, claim 4 is canceled. It was agreed that claims 17 and 20 should depend from independent claim 21.

Therefore, claims 17 and 20 are amended as follows:

17. (previously presented) The process according to ~~claim 4~~ claim 21, wherein the step of stopping the crosslinking is carried out by dialysis.

20. (previously presented) The process according to ~~claim 4~~ claim 21, wherein the polymers are of natural origin.

REASONS FOR ALLOWANCE

The following is an Examiner's Statement of Reasons for Allowance of pending claims 2-3, 5-9, 11-12, and 15-28:

The prior art does not teach or suggest Applicants' claimed process for the production of a biocompatible cross-linked polydensified monophasic gel consisting of the successive steps of a) starting a crosslinking reaction of a predetermined quantity of at least one biocompatible polymer in solution by the addition of a quantity of crosslinking agent in a first volume of a reaction mixture, b) crosslinking said quantity

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of polymer, c) adding a supplemental quantity of polymer of a molecular weight higher than 500,000 Da in solution with dilution of the reaction mixture so as to decrease an overall concentration of the polymer in a second volume of the reaction mixture, d) continuing crosslinking in the second volume of the reaction mixture, and e) stopping the crosslinking reaction by elimination of the crosslinking agent, to produce the monophasic gel; wherein the cross-linking reaction can be initiated in a basic or acidic medium, a supplemental quantity of crosslinking agent is added during the step of adding a supplemental quantity of polymer, and the step of stopping the crosslinking reaction is carried out by dialysis. Accordingly, the prior art also does not teach Applicants' claimed crosslinked, polydensified, monophasic gel prepared by the unique process and that comprises at least one dispersed active agent; or Applicants' claimed method to separate, replace, or fill a biological tissue or increase the volume of said tissue or to supplement or replace a biological fluid comprising injecting the gel into the said tissue.

The closest prior art is Ågerup (U.S. Patent No. 5,827,937), directed to a process for the production of a biocompatible, crosslinked gel comprising a) starting a crosslinking reaction of a predetermined quantity of at least one biocompatible polymer in solution by the addition of a quantity of crosslinking agent, b) crosslinking, c) diluting the reaction mixture (i.e. "sterically hindering the crosslinking") to slow or stop the crosslinking and obtain an activated polymer, d) re-introducing sterically unhindered conditions so as to continue the crosslinking to a viscoelastic gel; wherein the crosslinking reaction can be initiated in a basic or acidic medium and the step of

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reintroducing sterically unhindered conditions need not proceed under the exact same conditions as when initiating the cross-linking. Ågerup's teachings, however, absent improper hindsight, do not fairly suggest a process that does not involve the steps of "sterically hindering" to slow or stop the crosslinking reaction followed by reintroducing "sterically unhindered" conditions.

Therefore, pending claims 2-3, 5-9, 11-12, and 15-28 are found to be patentable.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee, and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID BROWNE whose telephone number is (571)270-1320. The examiner can normally be reached on Monday-Friday 8:30AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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